



Catalyst Pharmaceutical Partners Continues Clinical Development of CPP-109 For The Treatment of Cocaine and Methamphetamine Addiction

Company Reports Final Results of U.S. Phase II Cocaine Trial and Top-Line Results of U.S. Proof-Of-Concept Methamphetamine Study

CORAL GABLES, Fla., Sept 30, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Catalyst Pharmaceutical Partners, Inc. (Nasdaq: CPRX) today announced that the Company will continue to develop CPP-109 (Catalyst's version of vigabatrin) for the treatment of cocaine and methamphetamine addiction. The Company's decision was made after, and based upon, an in-depth review of the results obtained from its 186-patient Phase II clinical trial evaluating the use of CPP-109 for the treatment of cocaine addiction (CPP-01004) and the top-line results obtained from its 57-patient proof-of-concept study evaluating the use of CPP-109 for the treatment of methamphetamine addiction (CPP-02001). Catalyst's decision to continue the development of the drug for both indications was supported by a panel of experts who recently met and agreed with the Company's conclusion that there was sufficient evidence of safety and efficacy to justify further development of CPP-109, based upon these trial data and previously published studies of vigabatrin to treat addiction.

Cocaine Trial Results

After post-hoc analyses of vigabatrin levels in urine samples collected during the study, Catalyst concluded that less than 40% of the trial subjects were medication compliant. As a result, the study was inadequately powered to test the protocol-specified efficacy hypotheses. On the basis of a comprehensive review of all study data, however, it was concluded that: (i) CPP-109 was safe and well tolerated; and (ii) while there were no statistically significant differences between active and placebo groups for the protocol-specified primary and secondary efficacy endpoints, there were positive and consistent data trends observed in favor of CPP-109 across measures of cocaine abstinence, reduction in use, and reduction in use days.

Despite the limitations resulting from poor medication compliance by subjects, consistent trends in favor of CPP-109 over placebo were observed after the post-hoc analyses with respect to both primary and secondary efficacy endpoints. When corrected for poor medication compliance, the following favorable outcome trends were observed: (i) the log₁₀ benzoylecgonine (the major metabolite of cocaine) levels measured in urine collected from subjects were consistently lower in the CPP-109 treatment group during the 12 week treatment period, generally indicating a reduction of cocaine use; and (ii) in those subjects who were compliant with study medication, the differences between CPP-109 and placebo were amplified, which suggest that CPP-109 may facilitate abstinence, reduce overall cocaine use as measured by urine benzoylecgonine levels (an objective measure of daily cocaine usage), and reduce cocaine usage days (an objective measure of dependence severity).

Consistent with previous published addiction trials, the protocol in the Company's cocaine trial assessed subjects' medication compliance based on self reporting and on counting the unused medication returned by subjects. Based on that methodology, the Company had an 85% compliance level. However, after post-hoc testing of urine samples from many of the trial's subjects, the Company has concluded that less than 40% of the trial subjects were compliant taking their medication. As a practical matter, the low medication compliance effectively reduced the power of the study because not all subjects in the treatment group were actually treated. However, analyses of subject responses, corrected for poor compliance, makes the response ratios observed in the Company's trial more consistent with the results reported by Dr. Jonathan Brodie *et al.* in a double-blind, placebo-controlled, 103-patient Phase II trial evaluating vigabatrin for the treatment of cocaine addiction (the results of which were recently published on-line in *The American Journal of Psychiatry*).

Douglas Winship, Catalyst's Vice President of Regulatory Operations, commented, "The CPP-01004 clinical trial was a landmark first-in-class U.S. study and to our knowledge, the first large trial conducted in cocaine-dependent subjects of an orally administered medication in which extensive post-hoc objective measurements of medication levels in subjects to verify compliance were performed. Addicted subjects are an extremely difficult and unreliable population in which to conduct clinical trials. In addition, there are no established FDA guidelines for addiction trials. Based on numerous publications of data from previous addiction trials in which historical compliance rates of greater than 85% as measured by pill count and self-report were reported, we believed that our trial was sufficiently powered with 180 subjects. Unfortunately, due to the significantly lower verified actual compliance we found in our trial, there was insufficient power to detect a statistically significant difference between CPP-109 and placebo on the primary or secondary efficacy outcomes. We will continue to complete additional

analysis as part of our goal to present our results at appropriate medical conferences in the coming months."

Methamphetamine Study Results

The methamphetamine proof-of concept study enrolled 57 subjects (29 on vigabatrin and 28 on placebo) and there was a 2.5 times higher rate of abstinence in the last two weeks (11 and 12) of the study in the vigabatrin group versus placebo. While this is an encouraging trend, it was not statistically significant due to the small number of subjects in the study. Catalyst further believes that medication compliance may have been below expectations for this study as well.

CPP-109 (Vigabatrin) Safety Results

Regarding the safety of CPP-109, no clinically significant abnormalities in visual fields and visual acuity were found in any subject in either the cocaine or the methamphetamine trial. Furthermore, additional safety tests conducted in the methamphetamine trial revealed no brain or clinically significant cardiovascular abnormalities in any subject. Finally, no significant differences were found in the rates of adverse events between the CPP-109 and placebo treated subjects in either study.

Frank Vocci, Ph.D., President, Friends Research Institute and a former Director of the Division of Pharmacotherapies and Medical Consequences of the National Institute on Drug Abuse (NIDA), who participated in the experts panel, stated, "Based on expanded analyses from the Catalyst trial, compliant participants receiving vigabatrin tended to have fewer cocaine use days and generally lower cocaine metabolite levels in their urine than non-compliers. After reviewing these results and those from the recently published double-blind, placebo controlled trial conducted by Dr. Jonathan Brodie and his colleagues in Mexico, I believe CPP-109's favorable safety profile and the statistically significant 3.5 times increase in the achievement of abstinence with vigabatrin treatment that he reported, strongly support continuing the clinical development program for vigabatrin."

Patrick J. McEnany, Chief Executive Officer of Catalyst, stated, "There remains a tremendous unmet medical need for cocaine and methamphetamine addicted patients, and we believe a safe and effective patient-specific treatment may generate considerable interest among regulatory authorities, patients, physicians, investors and potential strategic partners. Our next step will be to present our findings to NIDA, the investment community, and potential strategic partners to obtain the funding to conduct additional clinical trials. We remain optimistic about the prospects for CPP-109 going forward and we are committed to aggressively pursuing our two primary objectives: (i) the continued development of CPP-109 towards a pivotal Phase III trial; and (ii) completing a high-value partnership for the CPP-109 program. With the addiction market potentially exceeding \$1 billion and growing, we believe CPP-109 is very competitively positioned from a safety and efficacy perspective."

Mr. McEnany concluded, "As a shareholder with a significant personal investment in the Company, my interests are aligned with the interests and concerns of every shareholder. I am deeply committed to building a successful Company."

About Catalyst Pharmaceutical Partners

Catalyst Pharmaceutical Partners, Inc. is a biopharmaceutical company focused on the development and commercialization of prescription drugs targeting diseases of the central nervous system with a focus on the treatment of addiction and obsessive-compulsive disorders. The Company has obtained from Brookhaven National Laboratory an exclusive worldwide license for nine patents in the United States relating to the right to use vigabatrin to treat a wide variety of substance addictions and obsessive-compulsive disorders. Catalyst has also been granted rights to Brookhaven's vigabatrin-related foreign patents or patents pending in more than 30 countries. The Company's initial product candidate based on vigabatrin is CPP-109. CPP-109 has been granted "Fast Track" status by the U.S. Food & Drug Administration (FDA) for the treatment of cocaine addiction. This indicates that the FDA has recognized that CPP-109 is intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrates the potential to address unmet medical needs. Catalyst has also recently been granted worldwide rights to another patented drug by Northwestern University. The Company intends to pursue development of this drug for several indications, including stimulant addiction and epilepsy. For more information about the Company, go to www.catalystpharma.com.

This press release contains forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties, which may cause the Company's actual results in future periods to differ materially from forecasted results. A number of factors, including the Company's ability to successfully obtain the financing required to perform future clinical trials of CPP-109 evaluating its use in the treatment of cocaine addiction and methamphetamine addiction, the Company's ability to successfully complete such future clinical trials that it determines to undertake, the Company's ability to successfully conduct such additional number of trials as may be required to file an NDA for CPP-109, and those other factors described in the Company's filings with the U.S. Securities and Exchange Commission (SEC), could adversely affect the Company. Copies of the Company's filings with the SEC are available from the SEC, may be found on the Company's website or may be obtained upon request from the Company. The Company does not undertake any obligation to update the information contained herein, which speaks only as of this date.

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